DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service 95/34d

Food and Drug Administration
PHILADELPHIA DISTRICT
900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106
Telephone: 215-597-4390

November 19, 2004

WARNING LETTER

05-PHI-01

FED EX

James Vercellotti, President
ATF Fitness Products, Inc.
140 Pennsylvania Ave.
Oakmont, PA 15139

Re: Sci-Fit Procuts

Dear Mr. Vercellotti:

In October 2004, Food and Drug Administration investigators Robert E. Davis and William H. Bender initiated an inspection of your establishment located at 140 Pennsylvania Avenue in Oakmont, PA. During that inspection, our investigators found that you have dietary supplement products that are labeled to contain materials that are sources of ephedrine alkaloids. For example, our investigator found that you have Sci-Fit Procuts, which is labeled to contain MaHuang Extract, a source of ephedrine alkaloids.

Under 21 CFR 119.1, dietary supplements containing ephedrine alkaloids are adulterated under section 402(f)(1)(A) of the Federal Food, Drug and Cosmetic Act (the Act) [21 U.S.C. 342(f)(1)(A)] because they present a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling, or if no conditions of use are recommended or suggested in the labeling, under ordinary conditions of use. It is a violation of section 301(k) of the Act to do any act with respect to a food, including a dietary supplement, while such article is held for sale after shipment in interstate commerce and results in such article being adulterated or misbranded. Furthermore, it is a violation of section 301(a) of the Act to introduce or deliver for introduction into interstate commerce any food, including a dietary supplement, that is adulterated. [21 U.S.C. 331(a).] You can find the Act and FDA's regulations through links on FDA's Internet web site at http://www.fda.gov.

During the inspection, we found evidence that you intend to ship the product Sci-Fit Procuts to a consignee in [redacted] In order to export a dietary supplement that may not be sold in the United States because it is adulterated, the product must meet the requirements of 801(e)(1), including that the product be intended for export. Furthermore, certain recordkeeping requirements listed in 21 CFR 1.101 must be met to demonstrate compliance with section 801(e)(1) of the Act [21 U.S.C. 381(e)(1)]. These records are as follows:

[redacted]

1) Records demonstrating that the product meets the foreign purchaser's specifications;
2) Records demonstrating that the product does not conflict with the laws of the importing country;
3) Records demonstrating that the product is labeled on the outside of the shipping package that it is intended for export; and
4) Records demonstrating that the product is not sold or offered for sale in the United States

During the inspection, you could provide no documentation to demonstrate your compliance with section 801 (e)(1) of the Act. If the requirements of 801(e)(1) are not met, the product cannot legally be exported and is subject to enforcement action under the Act.

This letter is not an all-inclusive review of products that your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. Please note that the finding of adulteration in 21 CFR 119.1 pertains to the Sci-Fits Procuts product and all other dietary supplement products at your establishment that contain ephedrine alkaloids.

We request that you promptly inform us of how you intend to dispose of these products. Failure to comply with the Act could result in enforcement action by FDA without further notice. The Act provides for the seizure of illegal products, injunctions against the manufacturers and/or distributors of violative products, and criminal sanctions against persons responsible for causing violations of the Act.

Please notify this office in writing within five (5) days of the receipt of this letter as to the specific steps you have taken to correct these violations, including any steps taken with respect to violative products currently in the marketplace, and an explanation of each step taken to assure that violations do not recur. Your reply should be sent to the Food and Drug Administration, Attention: Compliance Officer James C. Illuminati, at the address located in the letterhead.

Sincerely yours,

Thomas D. Gardine

Thomas D. Gardine
District Director
Philadelphia District